EXHIBIT J

FROM: **Bob Berenson**
SUBJECT: **8/2 Draft Options for DOJ's Alternative AWP Data**

HCFA has been considering options for acting on the alternative AWP data provided by DOJ for approximately 50 drugs. Requiring carriers to use these alternative AWP data instead of the usual AWP data, for example from the Red Book, would have the intended effect of reducing the current profit margins realized by providers and suppliers who bill Medicare for these drugs.

The Secretary informed Congressman Bliley that HCFA would send, in June, the DOJ data to carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which would become effective October 1, 2000. She informed the Congressman that this was the most immediate action HCFA could take without undergoing the formal rule-making process. She also indicated that HCFA would: 1) further explore with DOJ and IG the feasibility of developing additional means to ensure that accurate drug pricing data be used; 2) monitor carriers and require that they send to HCFA by September 15, 2000, an explanation of data sources used for determining payment allowances; 3) meet with the company that publishes the Red Book, to discuss recent developments and the need for accurate data; and 4) consider revising our current legislative proposal from paying 83 percent of average wholesales to instead propose paying physicians their actual acquisition costs.

Recently we have met with several provider groups to discuss what they believe would be unintended consequences of dramatic price changes for these drugs, particularly if a requirement to use the alternative AWP data is implemented immediately and without transition. In particular, we discussed drugs on the DOJ list that are used in treating hemophilia, ESRD, cancer, urologic condition and respiratory disease. Across these discussions, several common themes emerged including:

REDACTED

In addition to our discussions with provider groups, we have been analyzing data to determine what if any potential impacts we can glean from savings estimates. assuming the DOJ data are used as the AWP in determining drug allowances.

REDACTED

In light of our discussions and the impacts that our analysis suggest are possible, we have developed a number of options for your consideration. They are listed in the attachment.

8/2 Draft Options for DOJ's Alternative AWP Data

Option 1

Pros:

Cons:

REDACTED

Option 2

Pros:

Cons:

Option 3

REDACTED

Pros:

Cons:

Option 4 Pull-Back.

REDACTED

Pros:

Cons:

CY 1999 Data (95% complete)

Type of Service/ Medicare Dollars	Drug Dollars by Specialty	Percent of Total Revenue by Specialty	Total DOJ Drug Dollars	Total DOJ Drug Dollars by Specialty	Percent of Drug Dollars by Specialty	Total DOJ Dollar Savings	Percent Reduction per Drug	Percent of Revenue Reduction by Specialty	Offsetting Factor
ESRD (Independent Facilities Only) $4.4B	$450M	10.2%	$355M	$350M	98.6%	$93M	26.6%	2.1%	❑BBRA Comp Rate incr (1.2%=$30M) ❑Give-Back additional 1.2% ($30M) ❑Calcitriol and Iron Dextran are also in Oral form (non-covered) ❑$0.50 for supplies per encounter
DME Pharmacy $2.2B	$710M	32.3%	$293M	$290M	99.0%	$193M	65.9%	8.7%	❑Substitute Drugs for Albuterol ❑Rental/dispensation fee = $31M ❑DHHS Asthma initiative ❑OIG savings $47M-$115M depending on commercial AWP source ❑VA AWP - $200M savings
Urology $2.1B	$900M	42.9%	$637M	$570M	89.5%	$132M	20.7%	5.7%	❑Least Costly Alternative (Zoladex) in 37 States ❑Zoladex AWP<DOJ Lupron AWP
Oncology $2.4B	$1.6B	66.7%	$298M	$265M	88.9%	$169M	56.7%	6.3%	❑Chemotherapy administration PE = $130M ❑Increase number of pushes per day - currently only one per day
Hemophilia $90.7M	$90.7M	100.0%	$90.7M		100.0%	$29.7M	32.7%	32.7%	❑None
Misc $120M			$120M		N/A	$36.2M	30.3%	N/A	❑N/A
Sum =	$3.75B		$1.8B			$653M			❑N/A
Total Medicare	$4.5B		40.0%						❑N/A

NOTE: 22 drugs on this list are also pass thru drugs for O/P PPS.

08-02-2000

Federal Upper Limit (FUL)

This is a limit established in the Medicaid program and is defined in Medicaid regulations as 150 percent of the lowest price available in published sources. Medicaid has already determined the data sources to be First Data Bank, RedBook and Medispan as of January, 2000. The FUL does not relate to the DOJ price as it would apply to Medicare because the Medicare law requires 95 percent of the AWP.

08/02/2000 14:44 410-786-0192 HCFA PRESS OFFICE HCFA CHIEF 202 690 7159 PAGE 04
AUG-02-2000 12:49 P.01/01

TO BOB BERENSON
FROM CHRIS DERMA
1 PAGE
PER OUR DISCUSSION

Medicare price plan on hold

Doctors say excess drug payments offset costs

By Julie Appleby
USA TODAY, 3B, 8-2-00

WASHINGTON — A plan by Medicare to curb a practice that allows cancer doctors and home health agencies to overcharge for certain drugs has been delayed while health officials consider heated opposition from the groups affected.

The Health Care Financing Administration said it would send letters in June asking its Medicare bill payers to reimburse doctors using new, lower prices for a list of 50 drugs, mainly cancer and lung-disease treatments that must be administered by medical staff.

But the letters from Medicare have not gone out.

Cancer doctors have been arguing heavily against the change, warning that cutting their drug reimbursement without boosting their other Medicare payments will cause some doctors to stop providing in-office chemotherapy, potentially affecting 420,000 Medicare patients.

"What we've been telling our friends (in Congress) is that the Health Care Financing Administration should withdraw the proposal or Congress should stop them from implementing it until more studies are done," says Dr. Joseph Bailes, past president of the American Society of Clinical Oncology.

Bailes' group says doctors need the drug overpayments to offset paltry office-expense reimbursements by Medicare, which he says cover less than 25% of actual office costs.

A Health Care Financing Administration spokesman says Medicare remains committed to reducing overspending on drugs, "and plans to move forward shortly in a way that ensures we're paying correctly and also protects beneficiaries' access to services."

The plan to reduce Medicare billing for certain drugs stems from a long-running investigation by the Department of Justice and states attorneys general into drug-pricing practices that may be costing taxpayers more than $1 billion a year. The investigation, begun after a whistleblower complained, has been kept tightly under seal.

One issue under investigation is the ability of doctors, clinics and other medical providers to bill the federal Medicare program and state Medicaid plans for more than they actually pay for some drugs based on manufacturer-reported average wholesale prices.

For example, doctors can buy cancer drug doxorubicin for about $10 a dose but can charge the federal program $47. Home health agencies, which provide services for the homebound, could also be affected by the new prices.

The Department of Justice, as part of its investigation, developed revised prices for the drugs based on what doctors actually pay. In May, Justice sent those prices to state Medicaid directors, who are considering whether to use them.

Drug companies, however, say the Justice Department prices aren't accurate. Now, Medicare is considering using those numbers, too.

Rep. Tom Bliley, R-Va., chairman of the House Commerce Committee, is also investigating drug pricing. In May, he demanded that more than a half-dozen drug companies explain how they set average wholesale prices for products covered by Medicare and Medicaid.

The drug companies have complied, and Bliley's office is reviewing the information, says a spokesman, who added that Bliley is concerned that Medicare's plan to curb drug payments has been delayed.

"It's not Mr. Bliley's contention that sending out those new numbers is the best solution, but it was the solution suggested by (Health and Human Services Secretary Donna Shalala)," Bliley's spokesman, Peter Sheffield, says. "That they have not sent out those numbers is appalling."

TOTAL P.01